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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|-------------------------|
| 10/593,045 | 03/23/2007 | Yuhua Li | 69903 (301264) | 7310 |
| 90238 | 7590 | 03/01/2011 | EXAMINER | |
| Edwards Angell Palmer & Dodge LLP P.O. Box 55874 Boston, MA 02205 | | | | SAMALA, JAGADISHWAR RAO |
| ART UNIT | | PAPER NUMBER | | |
| | | | | 1618 |
| NOTIFICATION DATE | | | DELIVERY MODE | |
| 03/01/2011 | | | ELECTRONIC | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent@eapdlaw.com

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/593,045 | LI ET AL. | |
| | Examiner | Art Unit | |
| | JAGADISHWAR R. SAMALA | 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 35-47 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 35-47 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/22/2007</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Applicant's election of Group I claims 35-47 in the reply filed on 11/24/2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 03/22/2007 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

The drawings were received on 09/15/2006. These drawings are acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 35-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Volkonsky et al (US 6,482,436).

Volkonsky teaches magnetically controllable ferroccarbon particle composition comprising biologically active substance absorbed onto the particle. The particles have a major dimension of about 0.2 micron to about 5.0 micron and ratio of iron:carbon from about 95:5 to about 50:50, for example about 80:20 to about 60:40 (abstract and Col. 6 line 15-20). The carbon granules are activated carbon including various types like A, B, E, K and KB and chemically modified versions thereof (col. 9 line 5-8). The composition comprising iron:carbon particle including carbon and iron with the carbon distributed throughout the volume of the particle, and about 20% by mass of a biologically active substance adsorbed thereon for diagnosing or treating the disease (Col. 3, line 50+). The particles are capable of carrying biologically active compounds, which provide for targeted magnetic transport of the particles and the maintenance of them in a predetermined place for localized diaganostic or therapeutic treatment of disease. Additional disclosure includes that it is well known in the prior art to produce albumin microspheres containing a magnetic material and the anti-tumoral antibiotic doxorubicin and similar technique used to produce magnetically controlled or guided, mircocapsules covered with ethylcellulose containing the antibiotic mitomycin-C (Fujimoto S. et al., Cancer, 56, 2404-2410, 1985; see Volkonsky at col. 1, line 55-56).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a composition comprising composite particles of activated carbon and iron and an anticancer drug mitomycin C, because Volkonsky teaches that mitocmycin is known to be carried in microcapsules to provide an

anticancer agent (col. 1 line 45-55), because both Applicant and Volkonsky discloses compositions comprising such components.

Note: The amount of mitomycin C concentration in a pharmaceutical composition is clearly a result effective optimization parameter that a person of ordinary skill in the art would routinely employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of mitomycin C of active ingredient in order to achieve the desired results, such active agent absorbed onto magnetically targetable carrier particles for the treatment of cancer. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of mitomycin C concentration would have been obvious at the time of Applicant's invention. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Claims 35-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volkonsky et al (US 6,482,436) in view of S. Fujimoto et al (Cancer, 56, 2404-2410, 1985).

Claims are drawn to a magnetically targetable carrier composition comprising: composite particles of activated carbon and iron in the range of from about 95:5 to about 50:50 ration and wherein said particle includes mitomycin C.

Volkonsky teaches magnetically controllable ferrocarbon particle composition comprising biologically active substance absorbed onto the particle. The particles have a major dimension of about 0.2 micron to about 5.0 micron and ratio of iron:carbon from about 95:5 to about 50:50, for example about 80:20 to about 60:40 (abstract and Col. 6

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line 15-20). The carbon granules are activated carbon including various types like A, B, E, K and KB and chemically modified versions thereof (col. 9 line 5-8). The composition comprising iron:carbon particle including carbon and iron with the carbon distributed throughout the volume of the particle, and about 20% by mass of a biologically active substance adsorbed thereon for diagnosing or treating the disease (Col. 3, line 50+). Additional disclosure includes that the particles are capable of carrying biologically active compounds, which provide for targeted magnetic transport of the particles and the maintenance of them in a predetermined place for localized diagnostic or therapeutic treatment of disease.

Volkonsky fails to teach mitomycin C in the composition.

Fujimoto teaches composition comprising microspheres containing mitomycin C suitable for chemoembolization (abstract). Additional disclosure include that the mitomycin C microsphere treatment is superior at p=0.059 in survival duration to the conventional infusion treatment and as these microspheres are entrapped within the small vessels in the target tumor area, and release gradually into the area, thereby resulting in marked decline in systemic blood levels of mitomycin C microspheres. And also none of the patients experienced complications related to percutaneous catheterization and extrahepatic embolization after intra-arterial administration of mitomycin C microspheres.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate mitomycin C into Volkonsky's composition. The person of ordinary skill in the art would have been motivated to make those

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modifications because Volkonsky teaches that magnetically responsive carrier for biologically active substance has improved magnetic responsiveness, yet is durable during storage and use; and its efficacy in diagnosing or treating the disease which is adsorbed on the particles (col. 3 lines 45+). Therefore, one of ordinary skill in the art would have had a reasonable expectation of success because Volkonsky teaches that the delivery of biocompatible particles (including carbon and iron and a biologically active substance) to a selected location in a body, and more particularly, for targeted magnetic transport of the particles and the maintenance of them in a predetermined place for localized for diagnostic or therapeutic treatment of disease.

Note: The amount of mitomycin C concentration in a pharmaceutical composition is clearly a result effective optimization parameter that a person of ordinary skill in the art would routinely employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of mitomycin C of active ingredient in order to achieve the desired results, such active agent absorbed onto magnetically targetable carrier particles for the treatment of cancer. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of mitomycin C concentration would have been obvious at the time of Applicant's invention. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

/J. R. S./
Examiner, Art Unit 1618

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